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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,449	02/11/2004	Winthrop D. Childers	200309745-1	4805

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EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
03/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/777,449	CHILDERS ET AL.	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the amendment filed on 1/29/2008. Claims 1, 4, 5, 14, 15, and 28 have been amended and claims 2 and 3 have been cancelled. Currently, claims 1 and 4-28 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5, 8-15, and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (US 6,234,167) in view of Poole (US 6,158,431).

Regarding claims 1, 14, and 28, Cox et al. discloses an inhaler comprising a medicament supply (37), an ejector (29, 33) having a performance characteristic and a programmable controller configured to actuate the ejector using an operational parameter with a correction factor based on the performance characteristic of the ejector (column 7, lines 15-30 and column 8, lines 1-45). Cox et al. also discloses an accumulator (tube 27) in fluid communication with the ejector and a valve (35) intermediate the medicament supply and the accumulator (see Figure 1). Please note that the tube (27) is considered an accumulator as defined by the instant specification on page 3 as a volume in fluid communication with the ejectors. Cox et al. further discloses a pressure sensor (pressure drop sensing device; column 4, line 29) to sense the pressure in the accumulator. The valve (35) is configured to open and close in response to the sensed pressure

within the accumulator to regulate medicament pressure at the ejector (see column 4, lines 29-33 and lines 45-47; i.e., the valve opens upon a sensed pressure drop caused by inhalation near the end of the accumulator (27) and then closes after a predetermined amount of time). To the extent, if any, that Cox et al. is silent as to a correction factor, Poole teaches an inhaler having an ejector having a performance characteristic and a controller configured to actuate the ejector using an operational parameter including a correction factor based on the performance characteristic of the ejector (column 5, line 65-column 6, line 2, and column 7, lines 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a correction factor in the device disclosed by Cox et al. as taught by Poole in order to produce the desired performance characteristic (and thus, desired dosage) in a given environment and for a given user.

Regarding claims 4 and 5, Cox et al. discloses that the valve (35) intermediate the medicament supply and accumulator that is operated by the controller (see column 5, lines 20-45). Adjustment of the compliant member (45) would increase pressure in the accumulator.

Regarding claims 8-11, Cox et al. discloses that the operational parameters controlled can include drop ejection frequency, the dosage (i.e., total drops ejected), medicament pressure (via the valve), or ejector temperature (via a heater) (see column 6, lines 60-67, column 7, lines 15-30 and column 8, and lines 5-10).

Regarding claims 12 and 13, the correction factor disclosed by Poole can be considered static or dynamic. For example, as humidity changes, the correction factor changes accordingly (Figure 10) and would therefore be considered dynamic. However, if humidity remains the same,

the correction factor can be considered a static correction factor based on the drop drying length, temperature, and drop size.

Regarding claims 15 and 21-27, although Cox et al. as modified by Poole does not specifically disclose the recited calibration steps (i.e., determining a correction factor to produce the target output from the inhaler), the modified Cox et al. device has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. Specifically note that the controller of Cox et al. is programmable (column 8, lines 5-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified Cox et al. device, to perform the recited method steps of the instant claims in order to calibrate the inhaler. In addition, Poole explicitly discloses that the inhaler and sensors should be calibrated so that the desired performance characteristic can be achieved by varying the operational parameters (column 12, line 40-column 13, line 15).

Claims 6, 7, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. and Poole, as applied to claims 1, 4-5, 8-15, and 21-28 above, and further in view of Poole et al. (US 5,278,626).

Regarding claims 6 and 7, Cox et al. as modified by Poole does not explicitly disclose determining the ejected drop volume or weight. However, Poole does disclose that the droplet inspection determines the size, shape, and concentration of the droplets. Determining droplet volume or weight from this information is considered a design consideration to one of ordinary skill in the art. It appears that Poole's device is fully capable of determining droplet volume and weight from the collected information. In addition, Poole et al. teaches that determining volume

from droplet diameter in an inhaler is well known in the art (column 6, line 65-column 7, line 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use drop volume or weight for the performance characteristic instead of drop size for a more accurate determination of the amount of medication being delivered to the patient with each drop.

Regarding claims 16-20, the modified device disclosed by Cox et al., Poole and Poole et al. has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified Cox et al. device, to perform the recited method steps of the instant claim. In addition, Poole discloses calibrating the inhaler and sensors so that the desired performance characteristic can be achieved by varying the operational parameters (column 12, line 40-column 13, line 15).

Response to Arguments

Applicant's arguments filed 1/29/2008 with respect to the sensor (48) of Cox et al. have been considered and are persuasive. Sensor (48) only measures pressure within a separate chamber (47) holding pressurized gas (G) and the supply of fluid (37). Chamber (47) does not include accumulator (27) as previously interpreted by the examiner. However, the added limitation of the valve being "configured to open and close in response to a sensed medicament pressure within the accumulator" prompted the reconsideration of the Cox et al. reference in which the pressure drop sensing detector (column 4, lines 29) configured to control the opening/closing of the valve (35) was found to read on the amended claims. The amendment

involving the new limitation of the valve being configured to be opened and closed in response to the sensed pressure in the accumulator necessitated the reconsideration and new grounds of rejection and therefore, this Action is made Final.

In response to applicant's arguments involving the Poole et al. reference, examiner notes that Poole et al. was cited merely as evidence that it is well known that determining volume from droplet diameter in an inhaler is well known in the art. In response to applicant's arguments against the reference individually as not comprising all of the claimed elements, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/

Supervisory Patent Examiner, Art Unit 3771